IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
Case No: 5:16-CV-00410-BO

THE UNITED STATES OF AMERICA,
and THE STATE OF NORTH CAROLINA,
EX. REL. STEPHEN GUGENHEIM,

Plaintiffs,

v.

MERIDIAN SENIOR LIVING, LLC, ET AL.,

Defendants.

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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NATURE OF THE CASE

Relator Stephen Gugenheim ("Relator") commenced this *qui tam* action by filing a Complaint in camera and under seal on June 17, 2016. Relator alleges that Defendants—45 adult care homes that operate special care units and related entities and individuals—defrauded the State of North Carolina by submitting false claims for personal care services ("PCS"). An Amended Complaint, adding claims for conspiracy, was filed on June 26, 2017, and was subsequently unsealed. Defendants appeared on August 1, 2017. The Court dismissed Relator's claims for conspiracy on March 23, 2018.

Relator's theory is straightforward: he argues that North Carolina Medicaid's Clinical Coverage Policy 3L requires that PCS providers—regardless of setting—must bill only for the actual time spent providing PCS to Medicaid beneficiaries. Relator alleges that the number of hours worked by PCS aides at each of Defendants' facilities are fewer than the PCS hours billed. He concludes that this means that for the past six years, Defendants could not have provided the units of PCS billed and their claims for payment are fraudulent.

As the Court recognized in its summary of this case at the hearing on April 24, 2019, regarding discovery motions,

> The relator . . . believes that evidence will show that as for certain kinds of patients . . . that you look at the employment records of these nursing homes and the billings that have happened, the billings have been at one level and the staffing has been at a diminished level and so circumstantially implicit in that is that there is a padding or overbilling or under servicing the patients.

Tr. 2:2-22 (April 24, 2019) (App. 23). Relator's counsel responded "Yes, Your Honor, that's essentially the truth of the case." Tr. 2:23-24.

The evidence has not borne out that theory. According to NC Medicaid officials responsible for administering the PCS benefit, tracking or recording the amount of time spent

providing PCS "is not a requirement of our clinical coverage policy." Lea Dep. 111:5-111:9 (App. 136). Common sense dictates that if you are not required to track or record time spent, you cannot bill based on actual time spent. This is precisely why, since Policy 3L was implemented, adult care homes ("ACHs") have been instructed by NC Medicaid staff and written guidance to bill PCS based on completion of the service—not the time spent. "When that documentation demonstrates that the [PCS] service was rendered, and associated tasks, then the provider is permitted to bill for that service." Lea Dep. 52:5-15 (App. 125).

NC Medicaid has never interpreted Policy 3L to require any correlation between the units of PCS billed and the actual time spent providing PCS.

> The provision of services or care . . . and billing, are not always one to one. We permit providers to bill or require them to bill in fifteen-minute increments, units, service. However, we don't mandate that care . . . be delivered in fifteen-minute increments.

Lea Dep. 58:8-59:14 (emphases added) (App. 127-28). And NC Medicaid's communications to providers on this issue have been unequivocal. *See, e.g.*, Dep. Ex. 185 (June 9, 2015) (App. 504) ("The time spent on each task does not need to be recorded.").

NC Medicaid's undisputed testimony also makes clear that there is no information included (or omitted) from Defendants' billings that would materially affect its decision to pay the claims. Even after dozens of audits by NC Medicaid and the separate division responsible for licensing and regulating staffing levels, and more than three years after this case was filed, the government continues to pay Defendants' PCS claims.

Relator relies on an incorrect equivalency to prove his claim, disregarding the need to establish falsity, scienter, materiality, and causation. A False Claims Act case cannot be sustained on circumstantially implicit assumptions based on a faulty interpretation of Medicaid policies. With a flawed theory and no evidence of the essential elements—falsity, scienter, and

materiality—it is no surprise that the United States and the State of North Carolina have not intervened even after extensive discovery. Summary judgment is appropriate on all of Relator's claims.

STATEMENT OF FACTS

Pursuant to Local Civil Rule 56.1(c), Defendants cross-reference their Statement of Material Facts and its Appendix ("App.").

I. The Parties

A. Defendants

Forty-five of the Defendants in this case operate ACHs throughout North Carolina and provide PCS to elderly residents 24 hours a day, 7 days a week. *See* Map of Defendant Facilities, Stahlschmidt Decl. Ex. B. Medicaid is one source of funding for residents who cannot afford to pay for the room, board, and PCS provided by an ACH.

Many of the individual residents suffer from cognitive and memory impairments, such as Alzheimer's or dementia, that necessitate around-the-clock assistance and supervision. These individuals reside in parts of the ACHs with greater security and supervision called Special Care Units ("SCUs"). Defendants currently care for more than 1,300 Medicaid beneficiaries in SCUs. Stahlschmidt Decl. ¶ 31.

Defendant Affinity Living Group, LLC ("Affinity") manages the ACHs that are defendants in this case and others. Trefzger Dep. 13:21-16:12 (App. 141-44). Affinity's CEO, Charles E. Trefzger, Jr., is the lone individual defendant. Meridian Senior Living, LLC ("Meridian") was the entity that provided management services to the individual ACHs before February 2016. Starnes Dep. 29:10-16 (App. 29).

B. Relator

Relator has practiced law in North Carolina since 2001. Gugenheim Dep. 22:7-24:24 (App. 166-68). His practice focuses on medical malpractice with a "significant part" focused on suing nursing homes and assisted living facilities. *Id.* Relator has represented clients in suits brought against one or more Defendants at least seven times. First Am. Compl. [hereinafter FAC] ¶ 122 [DE 26]. During the course of that unrelated litigation, Gugenheim compiled information that he alleges supports his FCA claims in this case. *Id.* ¶ 123.

C. The Government

Despite being a real party in interest to this proceeding and its subject matter, the United States and the State of North Carolina (collectively "government") have chosen not to intervene. The North Carolina Department of Health and Human Services ("NC DHHS"), Division of Health Benefits ("DHB"), formerly "Division of Medical Assistance ("DMA") [hereinafter "NC Medicaid"] oversees the North Carolina Medicaid Program, including a benefit for PCS, which provide assistance with Activities of Daily Living ("ADLs") (i.e., bathing, eating, toileting, mobility, and dressing).

During discovery in this action, four NC Medicaid staffers provided testimony relevant to Defendants' Motion for Summary Judgment:

- Karen Feasel, Ph.D. – a former PCS Policy Analyst who developed relevant portions of the PCS program that were carried forwarded into Policy 3L. She played a major role in drafting the Clinical Coverage Policy governing PCS since January 1, 2013. Feasel Dep. 12:18-13:24, 29:10-30:7 (App. 31-32, 35-36).

- Cassandra McFadden - the current Program Operations Manager responsible for overseeing the PCS program. Ms. McFadden was PCS Policy Analyst from 2012 to 2013 and the PCS Unit Manager from 2015 to 2017. McFadden Dep. 12:17-14:13 (App. 54-56).

- Sabrena Lea – the current Associate Director for Long-Term Services and Support, which oversees numerous Medicaid services,

including PCS. Ms. Lea was the Chief of Home and Community Based Services who oversaw the PCS Program from late 2012 to 2015. Lea Dep. 7:6-8:23 (App. 118-19).

- Patrick Piggott – a current Associate Director for the NC Medicaid Office of Compliance and Program Integrity with responsibility for pre- and post-payment audits of claims for PCS reimbursement. Piggott Dep. 7:25-8:18 (App. 105-06).

II. The North Carolina Medicaid Benefit for Personal Care Services

PCS is a benefit provided under NC Medicaid to Medicaid beneficiaries who "have a medical condition, disability, or cognitive impairment and demonstrate unmet needs for hands-on assistance with qualifying activities of daily living ("ADLs"): bathing, dressing, mobility, toileting, and eating. Medicaid and Health Choice Clinical Coverage Policy No. 3L § 1.0 (Jan. 1, 2013) [hereinafter "Policy 3L"].[1]

A. History of Medicaid Coverage for PCS

Prior to January 1, 2013, PCS provided to Medicaid beneficiaries in North Carolina was treated differently depending on whether the services were provided in a private in-home setting or an ACH. Feasel Dep. 26:15-19 (App. 33). PCS provided by in-home providers required an independent assessment and was billed in 15-minute units based on the time spent in a person's home providing services. *See* Policy 3C, Dep. Ex. 189 (App. 170-99). PCS provided in ACHs, in contrast, was billed on a single per diem rate per resident. Feasel Dep. 26:6-19.

Effective January 1, 2013, the North Carolina State Medicaid Plan was amended combining PCS provided in any setting into a consolidated program. *See* SPA 12-013 (App. 288-302). To implement the consolidated PCS program, NC Medicaid created Policy 3L which carries

[1] Policy 3L became effective January 1, 2013. Dep. Ex. 32 (App. 347-71). Second and third version were adopted on November 1, 2015 and June 26, 2017, respectively. Dep. Ex. 181 (App. 618-61); Dep. Ex. 182 (App. 685-730). Except where noted, citations to Policy 3L are to the July 1, 2016 version, the version in place at the time the First Amended Complaint was filed.

forward to PCS providers in any setting most of the provisions of prior policies that were previously applicable only to in-home PCS. Feasel Dep. 67:6-16; 183:19-24 (App. 43, 52). Policy 3L contains all of the rules and regulations that govern providers with respect to PCS. McFadden Dep. 28:16-29:23 (App. 58-59).

B. Clinical Coverage Policy 3L

1. Independent Assessment and Prior Approval of PCS Hours

Policy 3L requires all beneficiaries to undergo an independent assessment to determine eligibility and preauthorization for PCS, regardless of setting. Policy 3L § 5.0 and Attachment A (App. 694, 729-30). Each ADL has several tasks associated with it (e.g., the bathing ADL includes shower, bath, hair care, nail care, and oral hygiene). *Id.* § 5.4.1 (App. 696). The independent assessment identifies the tasks with which a beneficiary needs assistance; the level of assistance needed; and the number of days per week on which assistance is needed. Policy 3L § 5.4.9 & Attachment A (App. 700, 729-30). The independent assessor then rates the beneficiary's "overall self-performance capacity for each ADL" (i.e. totally able, cueing, limited, extensive, or full assistance). *Id.*

Based on the needs identified in the independent assessment (task, level of assistance, and frequency), an algorithm determines eligibility for PCS benefits and calculates the monthly authorized hours of coverage. Policy 3L § 5.4.7 (App. 700). The algorithm uses estimates of the daily maximum amount of time needed to meet the need for either limited, extensive, or full assistance with each ADL. Feasel Dep. 66:2-16 (App. 42), 167:18-23 (App. 49); *see also* Policy 3L, App'x A (App. 727-28).

When Policy 3L became effective on January 1, 2013, a beneficiary could be approved for no more than 80 hours of PCS per month. Policy 3L § 5.4.2(b) (Jan. 1, 2013). Later in 2013, the

General Assembly authorized an additional 50 PCS hours[2] for beneficiaries with memory impairment who need increased supervision. S.L. 2013-306 (App. 372-74); *see also* Policy 3L App'x A. These additional 50 safeguard hours are approved based on exacerbating conditions and are not calculated by reference to any particular ADL or time estimates. McFadden Dep. 132:15-133:21 (App. 81-82).

2. Documentation Requirements

Policy 3L requires providers to create a person-centered "Service Plan"—a schedule of tasks to be performed—based on the needs identified in the independent assessment. Policy 3L § 6.1.4 (App. 706). Providers then execute the weekly Service Plan. Policy 3L requires providers to document only four items to show the performance of all PCS tasks in a beneficiary's Service Plan:

1. The date of service;
2. The tasks provided;
3. The name of the aide; and
4. Any deviations (care tasks not performed and the reason why).

Policy 3L § 6.1.5 (App. 707). Time is not one of the four items. *See* McFadden Dep. 179:9-13 (App. 87) ("When we talk about aide documentation and things like that, it talks about the completion of the task, not specifically the time spent on the task." (emphasis added)).

C. Time and Billing Under Policy 3L

The requirement that providers bill PCS in 15-minute units was carried forward into Policy 3L. However, ACH providers are not required to track or record time under Policy 3L. Policy 3L

[2] The General Assembly recognized and specifically referred to these extra hours as "additional safeguards." *See* S.L. 2013-306.

§ 6.1.5. The practical differences in how care is provided in-home and in ACHs means "we have a billing method that works well in an in-home care setting, and does not work well in an [ACH] setting." Feasel Dep. 111:16-112:18 (App. 46-47); *see also* McFadden Dep. 151:24-152:10 ("Folks in a primary private setting – they would be billing for their time in, their time out. When I think about an adult care home, I'm thinking about the fact that they completed the ADL.") (App. 83-84).

1. Policy 3L Does Not Require ACH Providers to Track Time

From the inception of the consolidated PCS program, NC Medicaid consistently advised ACH providers, verbally and in written guidance, that they are not required to record the time spent providing PCS. *See e.g.*, Dep. Ex. 168 at 42 (Nov. 11, 2012) (App. 249); Dep. Ex. 185 (App. 504) ("The time spent on each task does not need to be recorded.").

During their depositions, NC Medicaid officials repeatedly testified that ACH providers are not required to track or record time:

- Keeping the amount of time spent providing PCS "is not a requirement of our clinical coverage policy." Lea Dep. 111:5-111:9 (App. 136);
- "The policy doesn't specifically correlate the time back to the 15-minute units." McFadden Dep. 178:25-179:8 (App. 86-87);
- "When we talk about aide documentation and things like that, it talks about the completion of the task, not specifically the time spent on the task." McFadden Dep. 179:9-13.
- When asked if Policy 3L requires an aide or a provider to document the amount of time it took to provide a care task, Dr. Feasel stated, "No." Feasel Dep. 53:16-54:05 (App. 37-38).

- ACHs do not have to record time for providing services to a particular resident. Piggott Dep. 30:5-16, 33:8:-20 (App. 109-10).

The primary concern of NC Medicaid is that PCS is completed—not how long it takes. "Folks in a primary private setting – they would be billing for their time in, their time out. When I think about an adult care home, I'm thinking about the fact that they completed the ADL." McFadden Dep. 151:24-152:10 (App. 83-84); *see also* Policy 3L § 4.2.2(a)(2) (App. 692) (Medicaid will only cover PCS when it is documented as completed).

2. Complete the Task, Bill the Time

Despite the fact that ACH providers are not required to track time spent providing PCS, Policy 3L carried forward the billing model previously used only for in-home care providers. It defines a billing "unit of service" as 15-minutes. Policy 3L Attachment A (App. 730). However, Policy 3L does not link PCS care or authorized PCS hours "back to the 15-minute units." McFadden Dep. 178:25-179:8 (App. 86-87). Indeed, other than defining the billing units for PCS, Policy 3L "does not prescribe billing practices of any of our PCS providers." Lea Dep. 66:10-17 (App. 131).[3]

When asked about billing requirements under Policy 3L, Ms. Lea explained that the billing practices for an in-home setting "will vary from that of an ACH setting." Lea Dep. 48:5-18 (App. 122).

> Because the evolution of the PCS policy is imprecise in accounting for the fact that an individual resides in an adult care home 24 hours a day . . . when the provider can document that the task or the ADL was performed, they are permitted to bill for that unit**.**

Lea Dep. 51:1-22 (App. 124).

[3] Policy 3L states that "PCS follows wage and hour requirements for rounding billing units (7/8 rule). Policy 3L Attach. A ¶ E. However, Sabrena Lea clarified that "it's important to understand that in an ACH setting, the 7/8 rule is not applicable because of the setting." Lea Dep. 42:11-24 (App. 120).

This is the guidance given to Defendants by NC Medicaid: if at least one task associated with an ADL is completed, ACH providers may bill for all PCS units of time associated with that ADL. *See* Dep. Ex. 185 ("If the aide attempted the required task but it could not be completed, . . . if at least one of the remaining tasks could be completed for the same day, there is no requirement that time should be deducted from the billing of PCS hours." (emphasis added) (App. 505); McFadden Dep. 97:4-98:18, 104:10-14 (agreeing it is "accurate that if a provider does one of the ten tasks, then they can bill for that bathing—the time associated on the Appendix A in Policy 3L for the bathing ADL.") (App. 73-75).

If a beneficiary requires extensive assistance with the dressing ADL, 35 minutes would be allocated for that service. Policy 3L App'x A (App. 727-28). If a provider completed the tasks associated with the dressing ADL in 20 minutes, it is allowed to bill for 35 minutes of PCS. McFadden Dep. 113:5-114:22 (answering "yes" when asked if a provider could bill based on performance of a task "no matter how much time was spent") (App. 76-77).

Ms. McFadden testified that nowhere in Policy 3L does it mandate that "the number of labor hours of PCS aides . . . in an [ACH] for a week must be the same or greater than the number of PCS hours on a service plan." *Id.* 120:25-121:9 (App. 78-79).

3. Post-Payment Audits by NC Medicaid

NC Medicaid's Office of Compliance and Program Integrity ("OCPI") conducts post-payment audits of PCS claims. As part of those audits, OCPI looks to whether a task was completed by qualified staff; it does not look at the time spent providing PCS or the provider's level of staffing, or compare the hours worked with units of PCS billed. Piggott Dep. 28:20-30:16 (App. 107-09). NC Medicaid has never made a finding of noncompliance with Policy 3L based on an ACH provider's failure to document actual time spent or based on its staffing hours being less than

PCS units billed. Piggott (DHB) Dep. 15:13-24 (App. 115). In fact, if NC Medicaid personnel had a concern about staffing levels in an ACH, they would inform a different DHHS agency that licenses ACHs. *See* McFadden Dep. 202:14-204:15 (App. 94-96).

III. NC Medicaid Does Not Regulate ACH Staffing

The Division of Health Service Regulation ("DHSR") regulates and licenses all ACHs in North Carolina—whether they receive Medicaid reimbursements or not. 10A NCAC 13F .1308, entitled "Special Care Unit Staffing," sets out required staff-to-resident ratios. DHSR performs annual, unannounced inspections of licensed ACHs, including SCUs, to ensure compliance with licensing rules, including staffing levels. (App. 911-14). DHSR assesses penalties when staffing levels do not meet the required levels. *See* https://info.ncdhhs.gov/dhsr/acls/star/search.asp (last visited Sept. 18, 2019). Those penalties are separate and apart from North Carolina's Medicaid program.

Defendants' facilities have implemented various policies and procedures to ensure that the appropriate staffing ratios are met. For instance, Personal Care Aides ("PCAs") are required by policy to never leave their post until their replacement has arrived on site to begin their shift. Thompson Dep. 47:8-23 (App. 17). And in the event a PCA is scheduled to work but calls in sick or does not show up, then a supervisor, administrator, or other appropriate care provider is on call to cover that shift. *Id.* 47:24-48:7.

After implementation of Policy 3L, DHSR led a group of stakeholders to study the staff ratios in SCUs and whether they should be changed. *See* Dep. Ex. 194 (App. 443-58). The study group recommended no change to the staff ratios. *Id.*

ARGUMENT

Defendants[4] are entitled to summary judgment as a matter of law on all of Relator's claims under the False Claims Act (the "FCA"), 31 U.S.C. § 3729(a)(1)(A)-(B), and the North Carolina False Claims Act.[5]

"The False Claims Act is not an all-purpose antifraud statute, or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016) (quotation omitted). The plain language of Policy 3L, the guidance provided by NC Medicaid, and the testimony of NC Medicaid personnel responsible for the PCS program are consistent: ACH providers bill for the completion of PCS—not the time spent. No reasonable juror could return a verdict for Relator. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986).

To prevail on his claims, Relator must show:

> (1) that the defendant made a <u>false</u> statement or engaged in a fraudulent course of conduct;

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[4] As a preliminary matter, summary judgment is appropriate for individual Defendant Charles Trefzger. A corporate agent may be personally liable under the FCA in two ways: (1) under a corporate-veil-piercing theory; or (2) if that individual was directly involved in the alleged fraud. *See United States ex rel. Davis v. Prince*, No. 1:08CV1244, 2011 WL 13092085, at *5-7 (E.D. Va. June 23, 2011) (unpublished). Here, Relator cannot establish liability under either theory. Mr. Trefzger was not personally involved in generating, reviewing or submitting bills for PCS. He does not know what the members of the billing department review or consider in the course of their work. Trefzger Dep. 142:18-22 (App. 147). He summed up his knowledge of the billing operations as follows: "I do not know how they [the Affinity billing department] bill under Policy 3L." Trefzger Dep. 101:9-10 (App. 146). "The FCA is not a strict liability statute. It does not punish high-ranking individuals merely because of their association with a wrongdoing corporation." *U.S. v. Bertie Ambulance Service, Inc.*, No. 2:14CV53, 2015 WL 5916691, *5 (E.D.N.C. Oct. 8, 2015) (citation omitted).

[5] "The North Carolina False Claims Act is modelled after the federal act, and by its terms the North Carolina act is to be interpreted consistently with the federal act and the federal precedent." N.C. Gen. Stat. § 1-616(c). Throughout this Memorandum, all references to the FCA will include the North Carolina False Claims Act, unless otherwise indicated.

(2) such statement or conduct was made or carried out with the requisite scienter;

(3) the statement or conduct was material; and

(4) the statement or conduct caused the government to pay out money or to forfeit money due.

See U.S. ex rel. Harrison v. Westinghouse Savannah River Co., 352 F.3d 908, 913 (4th Cir. 2003) (emphasis added); *United States v. Odyssey Mktg. Grp., Inc.*, No. 5:15-CV-510-BO, 2017 WL 2484180 *6 (E.D.N.C. June 8, 2017). As the Supreme Court has explained, summary judgment is particularly appropriate for FCA cases because the standard for pleading and proving the elements is rigorous. *Escobar*, 136 S. Ct. at 2004 n.6.

IV. Falsity

To establish an FCA claim, the statement in question must be an "objective falsehood." *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008). Allegations of inefficient management or differences in interpretation of applicable requirements do not give rise to false claims. *Id.* at 377. "In the paradigmatic case, a claim is false because it 'involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.'" *United States v. Sci. Apps. Int'l Corp.*, 626 F.3d 1257, 1266 (D.C. Cir. 2010) (quoting *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001)). "A plaintiff asserting an FCA claim is still required to show that a false claim was submitted to the government." *U.S. ex rel. Grant v. United Airlines, Inc.*, 912 F.3d 190, 200 (4th Cir. 2018).[6]

Relator cannot establish that Defendants made objectively false claims for services they never provided. Rather, Relator relies on his incorrect interpretation of Policy 3L to hypothesize

[6] The Supreme Court in *Escobar* clarified that false or fraudulent statements include express falsehoods and misrepresentations by omission. 136 S. Ct. at 1999. There is no allegations here, however, that Defendants failed to disclose required or needed information.

that Defendants did not provide all of the PCS they billed because the hours billed were greater than staffing hours. Because, as discussed above, Defendants were not required to bill based on the actual time spent providing PCS, Relator's theory fails as a matter of law. Absent direct proof of claims for which services were not rendered, Relator's claims collapse.

A. Relator Has No Evidence to Support a Claim Based on Billings Before January 1, 2013

Relator alleges that Defendants submitted false claims for PCS reimbursement during "the relevant time period," which he defines as "2010 through the initial date of filing of Relator's Complaint and continuing thereafter." FAC ¶¶ 74, 164-172 [DE 26]. Relator's theory depends on the concept of billing for PCS in 15-minute units. Prior to the implementation of Policy 3L on January 1, 2013, reimbursement for PCS provided in an ACH had no reference to time at all and was based on a single per diem rate per resident. Feasel Dep. 26:6-19 (App. 33). Relator has not and cannot, as a matter of law, forecast evidence that Defendants falsely billed for PCS prior to January 1, 2013. All allegations of false claims submitted prior to January 1, 2013, fail.

B. Defendants Billed for PCS Completed After January 1, 2013

Relator cannot point to anything in Policy 3L or related guidance that requires ACHs to track the hours spent providing PCS. Similarly, there is no requirement that ACHs provide documentary evidence of the time spent providing PCS. While recognizing that Policy 3L calls for reimbursement claims to be submitted in units of 15 minutes, NC Medicaid's guidance and interpretation of Policy 3L to ACH providers has always been that if they complete the ADL service, they may bill for the time allocated to it. *See e.g.*, Dep. Ex. 185 (App. 505).

Testimony from the government agency that paid Defendants' claims unequivocally stating that the claims complied with applicable requirements defeats any allegation that the claims were false or fraudulent. *See U.S. ex rel. Searle v. DRS Tech. Servs., Inc.*, No. 1:14-CV-00403, 2015

WL 669197, at *13 (E.D. Va. Nov. 2, 2015) (granting summary judgment based on lack of falsity where defendant confirmed to the government's requirements for billing), *aff'd* 680 F. App'x 163 (4th Cir. 2017); *Odyssey*, 2017 WL 2484180 at *6 (summary judgment appropriate where defendant followed government instructions).

C. By Completing PCS, Defendants Met the Needs of the Residents

Relator also tries to bend the meaning of PCS "needs" to his advantage. FAC ¶¶ 103-08. This theory is again based on Relator's incorrect interpretation of the role time plays in an ACH and presumes that needs of the residents are defined by the authorized time for PCS. In fact, the needs of each Medicaid beneficiary are defined by the ADLs and related tasks for which they need assistance, the level of assistance needed with each task, and the frequency with which they need that assistance. *See* Lea Dep. 78:11-79:10 (App. 134-35).

The completion of the assistance with an ADL identified in the independent assessment is all that is necessary to "meet the needs" of the beneficiary. "So that's why when the provider can document the completion of that ADL, they are permitted to bill the number of units that were allocated for that, because it's tied to the delivery of the support that was identified to be needed for that individual with their ADLs." Lea Dep. 60:5-15 (App. 129).

D. NC Medicaid Does Not Condition Reimbursement on Compliance with Staffing Regulations

Relator's theory of this case assumes that Defendants understaffed their ACHs and failed to meet the needs of its residences. Any alleged violation of the licensing rules applicable to Defendants cannot lead to a claim of falsity. DHSR—not NC Medicaid—is the agency tasked with regulatory compliance. Lea Dep. 61:3-18 ("Staffing is a regulatory matter, and adult care homes are regulated by [DHSR].") (App. 130). Ms. McFadden, when questioned about understaffing and any relationship to Policy 3L, testified that if she had learned about any understaffing issues, she

would have referred the matter to DHSR and that information would have no impact on the government's decision to pay claims for PCS. McFadden 202:14-204:15 (App. 94-96). Compliance with licensing requirements is immaterial to payment by Medicaid, and there is no false statement.[7]

As the Fourth Circuit held, "the correction of regulatory problems is a worthy goal, but it is not actionable under the FCA in the absence of *actual fraudulent conduct*." *U.S. ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014) (quotations omitted, emphasis in original); *see also U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1221 (10th Cir. 2008) (regulatory compliance may be a condition to participation but violation of applicable regulations does not create a false claim). Here, Relator seeks to punish Defendants for what Relator sees as understaffing. The Fourth Circuit, however, expressly warned against using regulatory noncompliance as a proxy for falsity; "[w]ere we to accept relator's theory of liability based merely on a regulatory violation, we would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct." *Rostholder*, 745 F.3d at 702.

V. Scienter

The Relator cannot establish any evidence that Defendants acted with scienter. The FCA requires evidence that Defendants had actual knowledge of the allegedly false information and

[7] Relator is not arguing that Defendants certified compliance with licensing regulations as a condition to payment. No such certification is required by Policy 3L. Rather, Relator only argues that Defendants were out of compliance. Regardless, his claims fail. *See U.S. ex rel. The Boeing Co.*, 825 F.3d 1138, 1149 (10th Cir. 2016) (lack of compliance alone is insufficient to avoid summary judgment); *U.S. ex rel. Ketroser v. Mayo Foundation*, 729 F.3d 825, 829 (8th Cir. 2013) (summary judgment appropriate where Relator only relied on regulatory noncompliance with no evidence of an actual false claim).

either acted in deliberate ignorance or in reckless disregard of the truth or falsity of the information. *See* 31 U.S.C. § 3729(b)(1). Actions in reckless disregard require "an unjustifiably high risk" that was known or was "so obvious that it should [have been] known." *Safeco Inc. Co. of Am. v. Burr*, 551 U.S. 47, 68 (2007). Even if Relator's post hoc interpretation of Policy 3L is correct—which it is not—there is no evidence that Defendants knew or should have known they were submitting false claims. A defendant cannot have the requisite knowledge for an FCA claim where (1) the relevant governmental requirement is ambiguous, (2) the interpretation used by the defendant is objectively reasonable, and (3) there was no formal contrary government guidance. *See U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 878 (8th Cir. 2016); *see also U.S. ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518, 531 (6th Cir. 2012).

A. Defendants Followed NC Medicaid Guidance

Defendants' billing practices are consistent with NC Medicaid guidance. The contemporaneous written guidance from the Department and the subsequent deposition testimony of NC Medicaid Staff described above are consistent and indisputable: ACHs are not required to track or document the time spent providing PCS and ACH providers' billing is not based on the actual time spent providing PCS. If they provide the ADL service, ACH providers may bill for the time associated with that ADL.

NC Medicaid gave Defendants and other ACH providers instructions about Policy 3L. If Policy 3L was ambiguous or the Department gave the wrong instructions and that led to the submission of incorrect claims, there can be no finding of knowledge that the claims were false. *See U.S. ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) (where defendant submitted claims in accordance with government instructions, there could be no

finding of scienter). The Relator cannot create an issue of fact by imposing his own interpretation of Policy 3L on the State, and summary judgment is appropriate.[8]

B. Audits

State and federal regulators oversaw and audited the appropriateness of the claims that Defendants submitted to Medicaid during the relevant time period. During some of these audits, Defendants disclosed to the auditors and the PCS program's second in command—Ms. McFadden—that they were not documenting time spent providing PCS because they did not believe they were required to bill based on time spent providing PCS under Policy 3L. When informed of these matters, the auditors and high-level government officials never challenged Defendants' understanding and interpretation of the relevant regulatory requirements. *See e.g.*, Dep. Ex. 186 (App. 744-48). This undisputed fact defeats any theory that Defendants had any level of knowledge that they were operating incorrectly or improperly.

Since 2014, Defendants' facilities—which employ uniform and centralized billing processes—have been audited more than two dozen times. Stahlschmidt Decl. ¶ 13. None of those audits led to any questions, irregularities, or negative findings regarding billing of PCS. *Id.* ¶¶ 24, 30; *see also* Piggott (DHB) Dep. 15:13-16:9 (App. 115-16). The audits conducted by government regulators included Payment Error Rate Measurement ("PERM") audits performed by a contractor on behalf of the federal government; informal and formal audits conducted by NC Medicaid; and audits conducted by NC Medicaid's OCPI. Stahlschmidt Decl. ¶¶ 13-16; *see also* McFadden Dep. 47:13-21 (App. 62); Piggott (DHB) Dep. 13:13-20 (App. 114).

[8] As discussed above, what Relator seeks to do is to shoehorn an alleged failure to comply with licensing standards into a FCA claim. A violation of a government regulation, however, that is not a prerequisite to payment, does not establish the scienter necessary to establish a claim under the FCA. *See Rostholder*, 745 F.3d at 703 (finding no scienter where reimbursement statute did not address compliance with safety regulation).

In connection with a 2016 PERM audit, the federal contractor's standard document requests sent to Defendants included a request for timesheets and all documents showing the total time spent for the units billed to Medicaid. Stahlschmidt Decl. ¶ 25 & Ex. A; Dep. Ex. 186. Confused by this request, Tom Stahlschmidt, the person at Affinity who was charged with understanding the requirements of Policy 3L and responding to government audit requests, reached out to NC Medicaid. *Id.* Mr. Stahlschmidt communicated to Ms. McFadden, the PCS Program Manager, and Sue Helmke, the State PERM audit liaison, to explain Defendants' understanding that documents relating to time spent providing PCS were not required to be kept by Policy 3L, and that Defendants therefore did not have any materials in these (and other, related) categories requested by the PERM auditors. *Id.* Mr. Stahlschmidt wrote "Policy 3L dictates this is not applicable to PCS recipients residing in licensed residential facilities." *Id.*. Ms. Helmke responded, copying Ms. McFadden:

> The PERM reviewers will be using NC policies to review to see if what was billed to see if it met NC policy and billing requirements. Cassandra would need to provide clinical policy information to you that relates to policy. I would suggest that you send the FL2, 3050R, MD orders for sure.
>
> I will contact you if the PERM reviewers state something is missing or they need additional information. They will also send you a letter telling you what is missing. Please do not delay in sending the requested documents to the PERM contractor.

Id. (App. 744-48).

Mr. Stahlschmidt testified that no one ever contacted him to request further information related to this PERM audit, and that he was never further questioned about the absence of timesheets. Neither Ms. Helmke nor Ms. McFadden ever raised any doubt as to the appropriateness of Defendants' billing practices when so informed.

In another 2016 audit—this one conducted by DHHS's Office of Program Integrity—the State's auditors reiterated what Mr. Stahlschmidt and Defendants had long believed to be the case: that the documents required to be kept to support billing for PCS differed between ACHs and Home Health Agencies. State auditors acknowledged that fact in a 2016 audit records request, in which they wrote:

> PCS Provider, please note that the type/content of the record/ documentation/information requested may vary based on the applicable laws/regulation that govern the PCS billing provider entity (home care agency or residential facility).

Stahlschmidt Ex. B. The same record request thereafter requested that home-health agencies produce certain "Time Sheets" (among other records). *Id.* However, time sheets were not included in the documents requested of ACH providers, in apparent recognition of the fact that ACHs are not required to document and bill in the same manner as home health agencies.

The government's conduct and communications with Defendants with respect to the multiple audits of Defendants' billing is unrebutted, and supports the reasonable inference that Defendants lacked any knowledge—or even basis to question—that their method of billing PCS was improper. The government never gave any indication that the methods and procedures used by Defendants were improper. This unrebutted evidence demonstrates an absence of scienter and forms an insurmountable bar to Relator's claims. *See Williams*, 696 F.3d at 531 (summary judgment proper where Defendant had consulted with the government about the applicable regulation).

C. At Worst, Policy 3L is Ambiguous as to Billing by ACH Providers

Here, at worst, Policy 3L is ambiguous as to whether time plays any role in billing for PCS. Such ambiguity cannot be exploited by Relator to create a FCA case. As Ms. Lea and Ms. McFadden testified, NC Medicaid does not prescribe billing practices, and Policy 3L is silent about

reimbursement based on time. Ms. McFadden pointed this fact out at least three times during her deposition. Lea Dep. 66:10-17 (App. 131); McFadden Dep. 182:20-183:6 ("The policy doesn't speak specifically to time and indicating whether or not they should bill based on specific time. It's not clear."), 183:20-184:14 ("The policy doesn't speak to claims for reimbursement. . . . It is not clear or silent on the reimbursement practices."), 184:20-185:6 ("I don't think the policy is clear on the reimbursement of the PCS.") (App. 90-93).

Defendants interpreted Policy 3L to require only that the tasks be completed before they can be billed. Relator cannot show that such an interpretation was unreasonable particularly where the policy is silent as to the role of time in billing. *U.S. ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 829 (8th Cir. 2013) ("[Defendant's] reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA."). The government's guidance confirmed that interpretation.

In addition, Relator cannot overcome the industry evidence that other similarly situated ACHs billed without reference to time. *See U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018, 1020 (7th Cir. 1999) (differences in interpretation are not false, and defendant who was working with the government to achieve compliance was not knowingly submitting false claims.). Hugh Campbell, the Treasurer and Chief Financial Officer of Hedgehog Healthcare Associates, LLC ("Hedgehog") confirmed that NC Medicaid officials were aware that ACHs operated by Hedgehog were not tracking time and that Hedgehog bills PCS without regard to the amount of time expended to perform the services. Campbell Decl. ¶¶ 2, 12-14; *see also* O'Neill Decl. ¶¶ 9-11.

VI. Materiality

Under the FCA, materiality means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money of property." 31 U.S.C. § 3729(b)(4). "Materiality

looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar,* 136 S. Ct. at 2002 (quotations omitted).

"The materiality standard is demanding." *Id.* at 2003 (emphasis added); *see also id.* at 2004 n.6 ("The standard for materiality . . . is a familiar and rigorous one." (emphasis added). "The question of materiality is a mixed question of law and fact for the court to decide" and therefore, it is appropriate as a grounds to dispose of a claim on summary judgment. *United States ex rel. Harrison v. Westinghouse,* 352 F.3d at 914 (emphasis added); *see also Escobar*, 136 S. Ct at 2004 n.6 (rejecting argument that materiality is too fact intensive to dismiss a claim at summary judgment).

A. Actual Time is Not Material to Reimbursement for PCS Provided in ACHs

"There can only be liability under the False Claims Act where the defendant has an obligation to disclose omitted information." *U.S. ex rel. Berge v. Bd. of Trustees of the Univ. of Ala.*, 104 F.3d 1453, 1461 (4th Cir. 1997).

Ms. Lea expressly denied that actual time spent providing PCS is material to the decision to pay an ACH provider's claim for reimbursement. Lea Dep. 48:19-49:11 (App. 122-23). Ms. Lea explained that "in an ACH setting, tasks are a proxy for time" and that NC Medicaid does not require an accounting of time. *Id.* Rather, "we require the documentation of the accounting of tasks. Therefore, time and tasks are proxies." *Id.* This direct evidence is consistent with the guidance given to Meridian and other ACH providers since Policy 3L was implemented in 2013.

As discussed above with respect to falsity, Policy 3L itself, the government's written guidance, the government's audits, and the testimony by NC Medicaid staff make clear that the actual time spent by ACH providers is not material to payment of ACH providers' claims. This evidence is dispositive of the materiality element of Relator's claims.

B. Staffing Levels are Not Material to Reimbursement for PCS Provided in ACHs

"[S]tatutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment." *Escobar,* 136 S. Ct. 1989. Here, Relator points to Defendants' staffing as "inadequate." However, staffing levels are not prescribed or even addressed in Policy 3L. Lea Dep. 77:7-78:10 ("Medicaid does not regulate the staffing of adult care homes.") (App. 133-34). Therefore, the staffing levels of an ACH are not material to NC Medicaid's payment of PCS claims—as long as the services are provided. *See supra* Part IV.D. To be clear, neither NC Medicaid nor Defendants contend that staffing levels are not "important." They are simply not conditions of payment for PCS claims.[9]

C. The Government's Conduct Before and After Relator Disclosed His Claims to the Government Entitle Defendants to Summary Judgment

The guidance provided to Defendants by NC Medicaid since Policy 3L became effective, the testimony of NC Medicaid staff who oversee Policy 3L, and the government's failure to act both before and after Relator filed his complaint are undisputed evidence that show Relator cannot bear his burden that alleged misrepresentations in Defendants' claims were material to their payment.

> [P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in

[9] As stated above, DHSR—not NC Medicaid—regulates staffing and other operational aspects of Defendants' ACHs and has the ability to levy fines and other penalties for non-compliance.

> position, that is strong evidence that the requirements are not material.

Escobar, 136 S. Ct. at 2003-04.

Since Policy 3L became effective in 2013, NC Medicaid knew that Policy 3L did not fit well with ACHs because the provision and billing of PCS in ACHs differed from the in-home care model. *See* Feasel Dep. 110:14-21 (noting that "unfortunately" Policy 3L is billed in units of time "[b]ecause it's easy to apply time-based billing units in an in-home setting, and it's not easy to apply it in ACH"), 111:13-112:18 (explaining the differences between in-home care and ACH PCS noting, "[i[t means we have a billing method that works well in an in-home care setting, and does not work well in an adult care home setting") (App. 45-46). Based on the realities of this difference, NC Medicaid instructed ACH providers that PCS time did not need to be documented.

Relator can point to no evidence that the government has consistently refused to pay ACH providers' claims on the grounds that they are not based on the actual time spent providing PCS. Instead, the government has regularly paid the PCS claims of Defendants and other ACH providers. Coffey Decl. ¶ 9; Campbell Decl. ¶ 14; O'Neill Decl. ¶ 11. And it has continued to pay Defendants claims throughout this litigation. Coffey Decl. ¶ 10. The direct testimony of the NC Medicaid officials responsible for creating and administering the consolidated PCS program ends the inquiry as far as materiality goes.

After *Escobar*, other courts applying the materiality standard have dismissed cases similar to this one where a relator attempts to rely on conjecture about government payment decisions. *See U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1032 (D.C. Cir. 2017) (affirming summary judgment for defendant and stating, "courts need not opine in the abstract when the record offers insight into the Government's actual payment decisions"); *U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 489-91 (3d Cir. 2017) (materiality not established based in part on

fact that federal government continued to contract with defendant for 6 years after relator's disclosure in *qui tam* complaint of defendant's false certifications and declined to intervene in the *qui tam* lawsuit); *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) (fact that government did not deny reimbursement for device used in clinical trial after defendants allegedly made fraudulent representations about the device to the government "casts serious doubt on the materiality of the fraudulent representations that [relator] alleges"); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016) (affirming summary judgment for defendant where "the subsidizing agency and other federal agencies in this case have already examined [defendant] multiple times over and concluded that neither administrative penalties nor termination was warranted.").

Analyzing these "well-considered opinions," the Fifth Circuit drew the "lesson . . . that, though not dispositive, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality." *U.S. ex rel. Harman v. Trinity Indus.*, 872 F. 3d 645, 663 (5th Cir. 2017) (emphasis added). *Harman* reversed the district court's denial of a motion for judgment as a matter of law after a jury found the defendant's false certifications regarding the safety of highway guardrails were material to government decisions to reimburse defendant for installation of the guardrails. *Id.* The Fifth Circuit noted the government—after knowledge of the relator's claims—continued to reimburse defendant for guardrail installation, declined to intervene in the *qui tam* action after a ten-month review, and declined to produce government officials to testify on behalf of the relator. *Id.* at 665, 668-69. Accordingly, the Court held the defendant was entitled to judgment as a matter of law on the issue of materiality. *Id.* The Fifth Circuit cautioned that the FCA is designed "to vindicate fraud on the federal government, not second guess decisions made by those empowered through the democratic process to shape public policy." *Id.* at 668-69.

> The judgment before us falls far short of the FCA's true setting and fails to account for its congressional purpose in drawing upon private litigation to protect public coffers. The government has never been persuaded that it has been defrauded. . . .
>
> For the demands of materiality adjust tensions between singular private interests and those of government and cabin the greed that fuels it. As the interests of the government and relator diverge, this congressionally created enlistment of private enforcement is increasingly ill served. When the government, at appropriate levels, repeatedly concludes that it has not been defrauded, it is not forgiving a found fraud—rather it is concluding that there was no fraud at all.

Id. at 669-70.

Here, as in *McBride*, *Petratos*, *Kelly*, *D'Agostino*, *Sanford-Brown*, and *Harman*, the government considered and rejected Relator's allegations. Relator may disagree with the government's interpretation and administration of Policy 3L, but the FCA exists to protect the government—not to enrich private litigants. *See U.S. ex rel. Sanders v. N. Am. Bus Indus., Inc.*, 546 F.3d 288, 299 (4th Cir. 2008) ("[Relator] may think that [the government's] decision was wrong, but that does not make [defendant's] statements materially false.").

Despite having actual knowledge of Defendants' procedures and billing practices for PCS no later than June 17, 2016, when the Relator filed his Complaint, more than three years later, neither the federal nor state government has intervened in this action. Instead, the government continues to pay Defendants' claims for PCS based on completion of the service rather than actual time spent. Coffey Decl. ¶ 10; *see also* McFadden (Vol. II) Dep. 21:13-22:11 (testifying that she is not aware of any change in NC Medicaid's payments to Defendants for its PCS claims) (App. 100-01).

At the very least, based on NC Medicaid's continued payment, Defendants are entitled to judgment as a matter of law on any of Relator's claims related to claims submitted for PCS on or after June 17, 2016, because the government indisputably had actual knowledge of the alleged

false nature of those claims from receipt of the Complaint and Relator's disclosures. When the government pays a claim with actual knowledge of its alleged falsity, that is "very strong evidence" that the alleged falsities are not material. *Escobar*, 136 S. Ct. at 2003-04; *see also Becker*, 305 F.3d at 289 (holding that, in the Fourth Circuit, knowledge by the government can prevent a finding of scienter).

CONCLUSION

Relator cannot create an issue of material fact to keep his FCA claims alive by advancing an erroneous interpretation of Policy 3L. The undisputed facts show that Defendants billed for PCS in accordance with the guidance given to them by NC Medicaid. In the face of this guidance and the testimony of key NC Medicaid staff, Relator's parsing of an imperfect clinical coverage policy cannot render false each and every one of Defendants' claims made over a period of more than five years. Therefore, Defendants' Motion for Summary Judgment should be granted.

Respectfully submitted, this the 18th day of September, 2019.

/s/ Kimberly M. Marston
Jim W. Phillips, Jr.
N.C. State Bar No. 12516
jphillips@brookspierce.com
Jennifer K. Van Zant
N.C. State Bar No. 21280
jvanzant@brookspierce.com
D.J. O'Brien III
N.C. State Bar No. 35481
dobrien@brookspierce.com
W. Michael Dowling
N.C. State Bar No. 42790
mdowling@brookspierce.com
Kimberly M. Marston
N.C. State Bar No. 46231
kmarston@brookspierce.com
BROOKS, PIERCE, McLENDON,
HUMPHREY & LEONARD, LLP
P.O. Box 26000
Greensboro, NC 27420
Telephone: 336-373-8850
Facsimile: 336-378-1001

Attorneys for the Defendants

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing document complies with the word count limits established in Local Civil Rule 7.2(f)(2). Specifically, the document contains 8,371 words, as counted in compliance with Local Civil Rule 7.2(f)(3) and (f)(4).

/s/ Kimberly M. Marston
Kimberly M. Marston

CERTIFICATE OF SERVICE

I hereby certify that on September 18, 2019, a true and correct copy of the foregoing was filed electronically with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to counsel of record in this matter.

Clifford C. Marshall, Esq.
cmarshall@mrglawfirm.com

Jeremy Richard Williams, Esq.
jeremy@wbmllp.com

Steven K. McCallister
SmCCallister@ncdoj.gov

Katherine M. McCraw
kmccraw@ncdoj.gov

Joshua B. Royster, Esq.
joshua.royster@usdoj.gov

Matthew E. Lee, Esq.
matt@wbmllp.com

C. Michael Anderson
michael.anderson7@usdoj.gov

/s/ Kimberly M. Marston
Kimberly M. Marston